UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,912	10/10/2001	Daniel R. Soppet	1488.0620003	5683

22195 7590 10/23/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/972,912	SOPPET ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- Th MAILING DATE of this communication appears on the cov r sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 13, drawn to an isolated nucleic acid molecule encoding a polypeptide, classified in class 536, subclass 23.5.

II. Claims 10, 11, 14, drawn to a polypeptide, classified in class 530, subclass 350.

III. Claims 12, 15, drawn to an antibody, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of Invention I are related to the polypeptides of Invention II by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis or purification form the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

The polynucleotide of invention I and the antibody of Invention III are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for

antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The polypeptide of invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

If group I is elected Restriction to one of the following inventions is required under 35 U.S.C. 121:

Ia. a polynucleotide having a nucleotide sequence at least 95% identical to a nucleotide sequence encoding amino acids -32 - 365 of SEQ ID NO: 2.

Ib. a polynucleotide having a nucleotide sequence at least 95% identical to a nucleotide sequence encoding amino acids -31 - 365 of SEQ ID NO: 2.

Ic. a polynucleotide having a nucleotide sequence at least 95% identical to a nucleotide sequence encoding amino acids 1 - 365 of SEQ ID NO: 2.

Id. a polynucleotide encoding a polypeptide wherein, except for one to fifty conservative amino acid substitutions, said polypeptide has a nucleotide sequence encoding a amino acids -32 - 365 of SEQ ID NO: 2.

Ie. a polynucleotide encoding a polypeptide wherein, except for one to fifty conservative amino acid substitutions, said polypeptide has a nucleotide sequence encoding a amino acids -31 - 365 of SEQ ID NO: 2.

If. a polynucleotide encoding a polypeptide wherein, except for one to fifty conservative amino acid substitutions, said polypeptide has a nucleotide sequence encoding a amino acids 1 - 365 of SEQ ID NO: 2.

The inventions are distinct, each from the other because of the following reasons:

The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other: Ia and each of Ib-If;Ib and each of Ic-If;Ic and each of Id-If;Id and each of Ie-If;Ie and If.

If group II is elected Restriction to one of the following inventions is required under 35 U.S.C. 121:

IIa. a polypeptide having an amino acid sequence at least 95% identical to amino acids -32 - 365 of SEQ ID NO: 2.

IIb. a polypeptide having an amino acid sequence at least 95% identical to amino acids -31 - 365 of SEQ ID NO: 2.

IIc. a polypeptide having an amino acid sequence at least 95% identical to amino acids 1 - 365 of SEQ ID NO: 2.

IId. a polypeptide comprising amino acids -32 - -22 of SEQ ID NO: 2.

IIe. a polypeptide comprising amino acids -4 - 40 of SEQ ID NO: 2.

IIf. a polypeptide comprising amino acids 46 - 57 of SEQ ID NO: 2.

IIg. a polypeptide comprising amino acids 62 - 73 of SEQ ID NO: 2.

IIh. a polypeptide comprising amino acids 78 - 87 of SEQ ID NO: 2.

IIi. a polypeptide comprising amino acids 92 - 110 of SEQ ID NO: 2.

IIj. a polypeptide comprising amino acids 119 - 144 of SEQ ID NO: 2.

IIk. a polypeptide comprising amino acids 152 - 186 of SEQ ID NO: 2.

IIl. a polypeptide comprising amino acids 200 - 219 of SEQ ID NO: 2.

IIm. a polypeptide comprising amino acids 230 - 240 of SEQ ID NO: 2.

IIn. a polypeptide comprising amino acids 248 - 258 of SEQ ID NO: 2.

IIo. a polypeptide comprising amino acids 314 - 336 of SEQ ID NO: 2.

IIp. a polypeptide comprising amino acids 344 - 353 of SEQ ID NO: 2.

IIq. a polypeptide wherein, except for one to fifty conservative amino acid substitutions, said polypeptide has a sequence of amino acids -32 - 365 of SEQ ID NO: 2.

IIr. a polypeptide wherein, except for one to fifty conservative amino acid substitutions, said polypeptide has a sequence of amino acids -31 - 365 of SEQ ID NO: 2.

IIs. a polypeptide wherein, except for one to fifty conservative amino acid substitutions, said polypeptide has a sequence of amino acids 1 - 365 of SEQ ID NO: 2.

The inventions are distinct, each from the other because of the following reasons:

The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other: IIa and each of

IIb-IIs;IIb and each of IIc-IIs;IIc and each of IId-IIs;IId and each of IIe-IIs;IIe and each of IIf-IIs;IIf and each of IIg-IIs;IIg and each of IIh-IIs;IIh and each of III-IIs;III and each of IIj-IIs;IIj and each of IIk-IIs;IIk and each of III-IIs;III and each of IIm-IIs;IIm and each of IIn-IIs;IIn and each of IIo-IIs;IIo and each of IIp-IIs;IIp and each of IIq-IIs;IIq and each of IIr-IIs;IIr and IIs.

If group III is elected Restriction to one of the following inventions is required under 35 U.S.C. 121:

IIIa. an antibody that binds a polypeptide having an amino acid sequence at least 95% identical to amino acids -32 - 365 of SEQ ID NO: 2.

IIIb. an antibody that binds a polypeptide having an amino acid sequence at least 95% identical to amino acids -31 - 365 of SEQ ID NO: 2.

IIIc. an antibody that binds a polypeptide having an amino acid sequence at least 95% identical to amino acids 1 - 365 of SEQ ID NO: 2.

The inventions are distinct, each from the other because of the following reasons:

The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other: IIIa and each of IIIb-IIIc;IIIb and IIIc.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: each of the species in claim.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
OCTOBER 21, 2003